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5-2019

**New Vaccine Surveillance Network-Acture Respiratory Infection
(NVSN – ARI) Refusal Rate Analysis: Inpatient vs. Emergency
Department**

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NEW VACCINE SURVEILLANCE NETWORK – ACUTE RESPIRATORY INFECTION (NVSN – ARI)

REFUSAL RATE ANALYSIS: INPATIENT VS. EMERGENCY DEPARTMENT

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ABSTRACT

Introduction: Children with acute respiratory infection (ARI) often present to hospitals. The Children's Mercy Hospital (CM) is one of seven sites across the United States within the New Vaccine Surveillance Network (NVSN) funded by the Center for Disease Control (CDC). This network conducts active surveillance of pediatric patients who present with respiratory illness to the inpatient (IP) floors at CM and Children's Mercy Kansas (CMK) as well as the CM-Adele Hall Emergency Department (ED).

Method: From December 1, 2016-July 20, 2018, research coordinators screened and approached CM ED and IP patients who presented with ARI symptoms in the past 13 days, were <18 years of age, and resided in Jackson County, Missouri. Families were asked to allow research staff to perform a questionnaire and collect a nose and throat swab from the ill subject. Patients refusing enrollment were compared by a number of variables (sex, race, ethnicity, insurance status, enrollment month, enrollment day of the week, and common symptoms). For patients refusing enrollment, research staff asked the family if they would be willing to share if they had a reason for declining participation.

Results: In this analysis, an "unknown" race is a proxy for patients claiming only Hispanic ethnicity without addition of a race such as White or Black, due to questionnaire design. For IP subjects, the percentage of Black study subjects enrolled was comparable to the percentage of Black study subjects refusing participation (42% enrolled, 37% refused). Some differences in percentages of White study subjects enrolling and refusing enrollment were found (49% enrolled, 39% refused). For ED subjects, some differences in percentage of White study subjects enrolling or refusing participation (22% enrolled, 14% refused) and Black study subjects (50% enrolled, 60% refused) were found. Approximately twice as many patients claiming "unknown"/Hispanic ethnicity were found to decline study participation in the ED (14% enrolled, 35% refused). For the months in question, families did not cite a specific reason for declining participation; the second most common refusal reason families cited was specimen collection.

Conclusion: Looking for trends in study refusals may assist research teams in adjusting study activities to encourage enrollment. More information is needed with the completion of S17-S18 to obtain additional data and compare findings between study seasons.

INTRODUCTION

Research staff systematically screen and approach IP and ED patients to request participation in the NVSN-ARI research study. All eligible and available patients are asked to provide a research nose and throat swab specimen, as well as to complete a questionnaire about the subject's illness.

There are 8 possible outcomes to the permission/assent process when an enroller approaches a family:

- 1 = enrolled
- 2 = refused
- Other non enrollment reasons:
 - 3 = Discharged (before able to approach)
 - 4 = Parent/LAR are not available during visit
 - 5 = MD/Medical Team refusal
 - 6 = Missed (called non-eligible at screening, upon review deemed eligible)
 - 7 = Does not speak English or Spanish
 - 9 = Spanish interpreter not available

Refusals are the highest non-enrollment reason and 40%-60% of eligible subjects refuse study enrollment. In this analysis, there were 5 categories into which the reasons that patients refusing study enrollment were classified by study staff:

- 1 = Specimen collection
- 2 = SSN/ITIN issue
- 3 = Getting discharged and doesn't want to stay
- 4 = No specific reason
- 5 = Other (a reason not captured by the four previous categories)

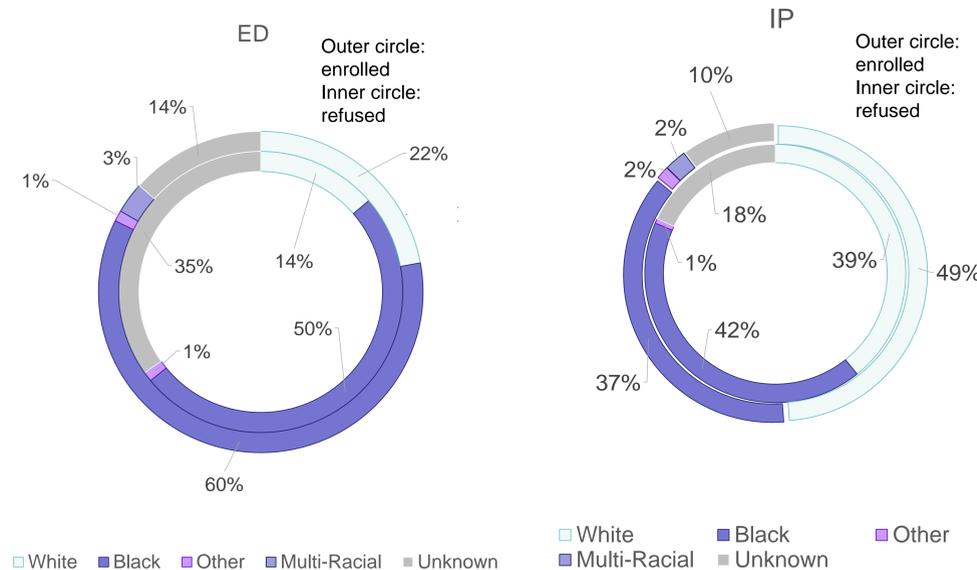
MATERIALS AND METHODS

Study design: ED ARI patients at CMH screened 4 days per week for 8hrs/day. The ED enrollment week runs from Sunday-Saturday and weekdays selected for enrollment are based on staffing levels. IP ARI patients are screened 5 days per week Monday-Friday for admissions occurring Sunday-Thursday.

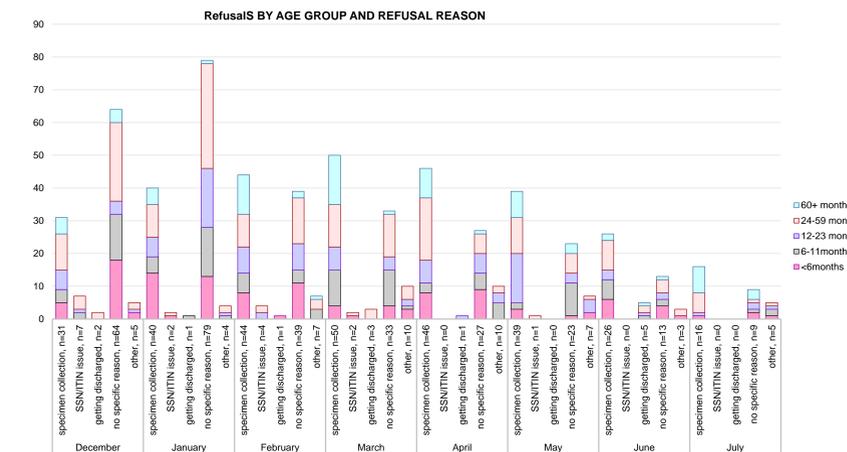
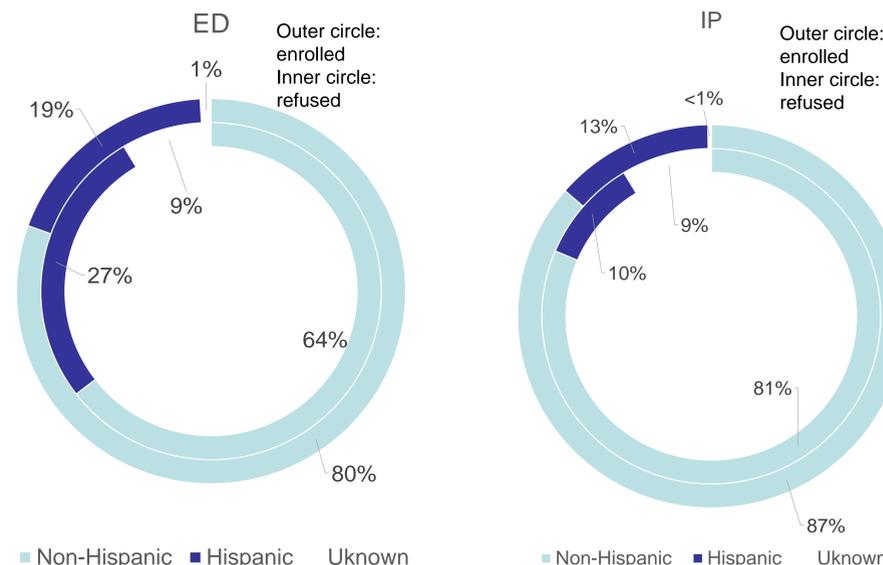
Study activities: Eligible and enrolled subjects underwent written permission/assent process, parent/legal guardian interviews, and mid-turbinate nasal and throat swabs were collected at the point of enrollment. After enrollment, discharge and other health information obtained from chart review. For subjects refusing participation, the family was kindly asked the reason for refusal.

RESULTS

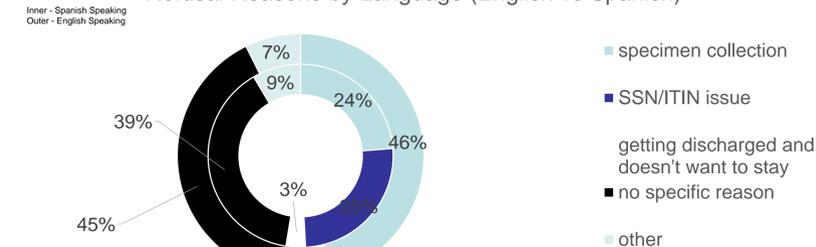
Refused vs. Enrolled - Race



Refused vs. Enrolled - Ethnicity



Refusal Reasons by Language (English vs Spanish)



CONCLUSIONS

Systematic examination of the demographics of patients refusing enrollment, and refusal reasons, may encourage improvement of research activities and therefore improve enrollment rates, or decrease the effect of high numbers of refusing participants.

Increasing numbers of non-enrolled subjects may affect the power of the study to answer the research question, so it is essential that study staff examine their standard procedures to determine if the standards can be revised.

More information is needed with the completion of future seasons to obtain additional data and compare the findings to this initial analysis. For example, since this initial analysis was completed, the requirement to obtain SSN/ITIN for all subjects receiving the Greenphire ClinCard has been removed. As a result, that has been removed as a refusal reason documented by study staff. Reviewing additional data may show a comparative difference in refusal reasons.

ACKNOWLEDGEMENTS

Thank you to the KC-NVSN team for their effort in enrolling for the NVSN-ARI study.

